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10/822,644

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Stephen R. Wilson

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EXAMINER

PURDY, KYLE A

ART UNIT

PAPER NUMBER

1611

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/822,644	<b>Applicant(s)</b> WILSON ET AL.	
	<b>Examiner</b> Kyle Purdy	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04/12/2004 and 12/05/2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 5-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 14, 15, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application***

1. In the previous office action, claim 13 was erroneously included in the group of pending/examined claims when it should not have been. In Applicants response to the election requirement of a substituted fullerene species on 09/28/2007, Applicants elected the species  $C_{60}( >C(COOH)_2 )_3$ , wherein the  $>C(COOH)_2$  moieties are in the C3 conformation. Applicant however did not elect said substituted fullerene species to include an endohedral metal. Therefore this claim should have been withdrawn in the previous office and is now being properly withdrawn.

2. Claims 1-15, 24 and 25 are pending, claims 4-13 and withdrawn and claims 1-4, 14, 15, 24 and 25 are presented for examination on the merits. The following rejections are made

### ***Response to Applicants' Arguments***

3. Applicants arguments filed 12/05/2007 regarding the rejection of claims 1-4, 14 and 15 made by the Examiner under 35 USC 112, first paragraph (enablement) have been fully considered and they are found persuasive. This rejection is withdrawn and has been modified to a scope of enablement rejection.

4. Applicants arguments filed 12/05/2007 regarding the rejection of claims 1-4 and 15 made by the Examiner under 35 USC 102(b) have been fully considered and they are not found persuasive.

5. Applicants arguments filed 12/05/2007 regarding the rejection of claims 1-4 and 15 made by the examiner under 35 USC 102(b) are **MAINTAINED** for the reasons of record in the office action mailed on 10/30/2007.

6. In regards to the 102(b) rejection, Applicant asserts the following:

A) Fumelli is silent regarding whether carboxyfullerenes would be effective in entering the skin of a living subject and Fumelli is silent to whether carboxyfullerenes would be effective *in vivo*.

7. With respect to assertion A, it is unclear how Applicants assertion pertains to the instantly rejected claims at hand. Claim 1 is directed to a method of ‘ameliorating a dermatological condition in the skin of a mammal comprising administering a composition comprising a substituted fullerene.....’. Nowhere in claim 1 or any subsequent dependent claim is there any requirement for the method to be performed *in vivo* nor is there any mention of carboxyfullerenes ability to enter the skin of a living subject. The only requirement of the instant claims is that the method be applied to the skin of a mammal to ameliorate a dermatological condition or potentially afflicted with a dermatological condition. Fumelli meets these basic requirements. Fumelli discloses a method of administering carboxyfullerene to keratinocytes obtained from human foreskin prior to exposure to UV-radiation to evaluate the ability of the applied carboxyfullerene to modulate the formation of sunburn. Thus, the method of Fumelli teaches administering a substituted fullerene to the skin of a mammal potentially afflicted with a dermatological condition.

***Maintained Rejections***  
***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**9. Claims 1-4 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Fumelli et al. (Society for Investigative Dermatology, 2000, 115:5, 835-841; of record).**

10. Fumelli is drawn to carboxyfullerene (CF) compositions and their use in protecting human keratinocytes from ultraviolet (UV) induced sunburn and apoptosis via scavenging of oxygen free radicals scavenging. It is taught that UV radiation is a major source of damage to the skin because UV radiation creates oxygen free radicals which can oxidize lipids, bind DNA and possible cause cell death (see page 835, right column, 2<sup>nd</sup> paragraph). Fumelli discloses a method of administering the C3 form of CF, specifically that of e,e,e-C<sub>60</sub>(COOH)<sub>6</sub> to normal human keratinocytes wherein the cells were pretreated with CF prior to UV exposure (see Materials and Methods section; see instant claims 1-4). Overall, it was found that CF is useful for protecting human keratinocytes from damage caused by free radical production (see page 836, left column, Figure 1). Such damage would include the formation of sunburn as well as tumors (see page 835, right column, 1<sup>st</sup> paragraph and page 840, left column, 1<sup>st</sup> paragraph; see instant claim 15).

11. Thus, Fumelli anticipates the instantly rejected claims.

***New Rejections***  
***Claim Rejections - 35 USC § 112***

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**13. Claims 1-4, 14, 15, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating dermatological conditions, does not reasonably provide enablement for preventing dermatological conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.**

14. There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court *In re Wands* (8 USPQ2d 1400 (FACF 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

15. The claims of the instant invention are drawn to a method of ameliorating a dermatological condition in the skin of a mammal, such as aging and psoriasis, comprising administering a substituted fullerene. These claims are quite broad and there is insufficient evidence to support the claims that the instant composition is actually capable of ameliorating such dermatological conditions. It is noted here that Applicant defines 'ameliorate' to encompass 'prevention' and 'treatment' of skin conditions, see [0026].

16. The skilled artisan would view the amelioration, especially the prevention, of a dermatological condition such as aging and psoriasis as unpredictable and dependent upon many complex chemical and biological factors. The current state of the art exemplifies as much. Weinert et al. (J. applied Physiology, 2003, 95, 1706-1716; of record) states that the ultimate causes of aging are likely to be dependent on molecular, chemical and genetic factors. Still, even though contributing factors are known, the ultimate causes of aging remains largely unknown (see page 1713, column 2, 2<sup>nd</sup> paragraph). As the ultimate causes of aging are unknown, Applicant has not sufficiently demonstrated any means for successfully preventing intrinsic aging. At best, Applicants method may be sufficient to minimize the chemical contribution to aging, but it does not critically demonstrate an ability to stop intrinsic aging processes involving molecular and genetic factors.

17. In the instant case, sufficient representative data is not present to support the claims that the method of administering substituted fullerenes is actually capable of ameliorating a skin condition. Applicant puts forth Figure 1 and Fig. 11 A-H as evidence to support the instant claims. However, the data provided is insufficient because it does not demonstrate the ability to prevent said skin conditions. Fig. 1 represents nothing at all. The mere presentation of only one treatment result does not lend any support to the efficacy of the method. Figs. 11 A-H are drawn to a chemical assay involving free radical inactivation which has nothing to do with ameliorating a skin condition. Specific and multiple working examples are critical in cases involving unpredictable and underdeveloped art. See MPEP 2164. The evidence provided is not commensurate in scope with the instantly claimed invention and does not critically demonstrate the claimed properties of the method.

***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**19. Claims 1-4, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fumelli et al. (Society for Investigative Dermatology, 2000, 115:5, 835-841; of record) in view of Hirsch et al. (US 7070810).**

20. Fumelli is relied upon for disclosure described in the rejection of claims 1-4 and 15 under 35 U.S.C. 102(b).

21. Fumellis fails to teach a method of administering an amphiphilic fullerene having the formula  $B_b-C_n-A_a$ .

22. Hirsch cures such a deficiency. Hirsch is directed to the synthesis and use of ‘buckysome’ carbon nanotubes for drug delivery. The compositions disclosed have the above  $B_b-C_n-A_a$  (BCA) structure (see column 2, line 25). It is taught that B is to be an organic moiety with at least one polar head group and A is an organic moiety having between 8 and 24 carbons (see column 2, lines 26-35; see instant claim 14). These nanotubes may include anticancer drugs such as paclitaxel and doxorubicin as well as other therapeutic agents like ibuprofen, acetaminophen and doxycycline (see columns 11 and 12). The nanotubes can be used for the treatment of cancers which include skin cancer (see column 8, 15-25; see instant claim 14).



23. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Fumelli and Hirsch with a reasonable expectation for success in arriving at a method of administering CF along with a BCA structure for the treatment of dermatological conditions. Fumelli is discussed above in detail. Briefly, Fumelli is directed to reducing the chance of sunburn and tumorigenesis of the skin by administering CF. Fumelli fails to include a BCA structure in their method. However, Hirsch cures this deficiency. Hirsch is directed to using BCA structures for administering drugs for the treatment of cancers which implicitly includes cancers of the skin. It would have been obvious to combine the two teaching because in doing so would provide a method of not only preventing the likelihood of tumorigenesis by administering CF but also provide a means for simultaneously treating a skin tumor by administering chemotherapeutic drug loaded BCA structures. Therefore, a method of administering CF as well as BCA structures in order to treat a dermatological condition is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

24.

**25. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fumelli et al. (Society for Investigative Dermatology, 2000, 115:5, 835-841; of record) in view of Dugan et al. (US 2003/0162837; of record).**

26. Fumelli is discussed above in detail.

27. Fumelli fails to specifically teach using a composition comprising between 0.01% to about 5% by weight of CF wherein the solvent medium of the fullerene composition is water.

28. Dugan is directed to CF and methods of use thereof. It is disclosed that fullerenes and derivatives thereof have potent antioxidant properties and such compounds act to reduce cell damage and death (see [0054]). It is disclosed that CF may be mixed with a variety of carrier materials such as water (see [0063]; see instant claim 25).

29. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Fumelli and Dugan with a reasonable expectation for success in arriving at a method of treating a dermatological condition by administering 0.01% to about 5% by weight of CF in a composition comprising water. Fumelli is discussed in detail above. Briefly, Fumelli motivates using CF for the treatment dermatological conditions. Fumelli fails to teach using a composition comprising between 0.01% to about 5% of CF wherein the carrier is water. Dugan is relied upon to show that CF is water soluble. With that said, Fumelli teaches that CF is to be used at a composition of 10 uM. This corresponds to a weight percentage of 0.8% when water is used as the solvent. Moreover, one would have been motivated to use water as solvent because it is frequently used as a delivery vehicle for topical formulations. Therefore, a method of administering between 0.01 to about 5% of CF in a water carrier is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

### ***Conclusion***

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

31. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

32. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/  
Examiner, Art Unit 1611  
August 5, 2008*

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